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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,121	03/24/2004	Joseph S.M. Peiris	V9661.0069	2460

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EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,121	PEIRIS ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☒ Claim(s) *17,27,30,146 and 174* is/are allowed ~~ed~~ abdw.

6)☒ Claim(s) *101,115,125,135,165 and 175-178* is/are rejected.

7)☒ Claim(s) *29 and 32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-17,20,21,23,25,27,29,30,32,54-56,58,60,62,75,77,79,81,89-101,108-111,115,121-125,130-133,135-139,144,146,151-154,158-163 and 165-178.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-16,20,21,23,25,54-56,58,60,62,75,77,79,81,89-100,108-111,121-124,130-133,136-139,144,151-154,158-163 and 166-173.

DETAILED ACTION

The examiner of your application in the Patent and Trademark Office has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Louise Humphrey, Art Unit 1648.

This Office Action is in response to the amendment filed 19 November 2006. Claims 18, 19, 22, 24, 26, 28, 31, 33-53, 57, 59, 61, 63-74, 76, 78, 80, 82-88, 102-107, 112-114, 116-120, 126-129, 134, 140-143, 145, 147-150, 155-157, and 164 have been cancelled. New claims 174-178 are added. Claims 1-17, 20, 21, 23, 25, 27, 29, 30, 32, 54-56, 58, 60, 62, 75, 77, 79, 81, 89-101, 108-111, 115, 121-125, 130-133, 135-139, 144, 146, 151-154, 158-163, and 165-178 are pending. Claims 1-16, 20, 21, 23, 25, 54-56, 58, 60, 62, 75, 77, 79, 81, 89-100, 108-111, 121-124, 130-133, 136-139, 144, 151-154, 158-163 and 166-173 are withdrawn. Claims 17, 27, 29, 30, 32, 101,115, 125, 135, 146, 165 and 174-178 are examined.

The priority date of the instant application is 23 April 2003.

Claims 146 and 174-177 are apparently free of prior art of the record. The closest prior art is the sequence of SARS corona virus strain TOR2, Genbank Accession No. AY274119.1 (14 April 2003) which matches 7914 contiguous nucleotides of SEQ ID NO:15.

Claim Rejections - 35 USC § 112, 1st ¶

The rejection of claims 101, 125 under 35 U.S.C. § 112, first paragraph, as being lack of enablement is withdrawn in view of Applicants' argument as set forth below, however, the rejection of claims 115, 135 and 165 under 35 U.S.C. § 112, first paragraph, as being lack of enablement is **maintained and extended** to new claim 178. Applicants' arguments have been fully considered but are not persuasive.

Applicants assert that based on studies of known coronaviruses (CoV), one skilled in the art would have been able to predict the characteristics of the viral proteins encoded by SEQ ID NO:15 without undue experimentation and use such information for therapeutic and/or vaccine purposes. The Examiner respectfully disagrees.

The state of the art, at the time of filing, is highly uncertain and unpredictable. The immune pathogenesis of SARS is not well understood. So far, no conclusive information is available on the immune correlates of protection to SARS in patients (Zhi, 2005). CoV replicate by a unique discontinuous transcription mechanism that is not completely understood (Navas-Martin, 2004), which makes it difficult to identify targets for anti-CoV therapeutic agents. More importantly, two major forces drive CoV evolution: recombination and mutation. CoV undergo homologous RNA recombination at high frequencies, although the mechanism is not well understood. It is well known that RNA viruses mutate at rates in the range of 10^{-3} to 10^{-5} base substitutions per nucleotide copied (Navas-Martin, 2004). These values are several orders of magnitude larger than those encountered during replication of DNA viruses, and many orders of

magnitude grater than of cellular DNA. As a consequence of this high mutation rates, RNA viruses exits as diverse populations composed of ensembles of closely related, non-identical genomes that are known as viral quasi-species. The molecular basis of this complexity is the limited copying fidelity exhibited by the viral replicases (Navas-Martin, 2004). As a result, some of variants will be able to evade the CD8 cytotoxic lymphocytic (CTL) response.

An ideal SARS vaccine should (1) elicit highly potent neutralizing antibody responses against a broad spectrum of viral strains; (2) induce protein against infection and transmission; and (3) be safe by not inducing any infection-enhancing antibodies or harmful immune or inflammatory responses (Jiang, 2005). The guidance presented in the specification is limited to the genome/protein sequence of a novel strain of SARS-CoV. The instant application does not disclose any B cell or T cell ($CD8^+/CD4^+$) epitopes, nor discloses any targets for the neutralizing antibodies, let alone any positive protective immune correlates of any 8000 contiguous nucleotides of SEQ ID NO. In general, both humoral and cellular immune responses are required to protect against CoV (Navas-Martin, 2004). The specification does not teach the immunogenic, pharmaceutical, and vaccine functions of any 8000 contiguous nucleotides of SEQ ID NO:15 that satisfies the criteria for a SARS therapeutic agent or vaccine as known in the art.

Considering the lack of data or working examples in the specification, the broad scope of the claims, the complex state and nature of the art, and the teachings

regarding unpredictability in this art, the Applicant has not provided sufficient information to enable those skilled in the art to make the claimed product without undue experimentation.

Claim Rejections - 35 USC § 102

The rejection of claims 18, 28, 31 and 146 under 35 U.S.C. §102(b) as being anticipated by the public use or sale of oligo-dT and oligo-U **is withdrawn** in view of the amendment.

The rejection of claims 17, 27, 30, 146 and 174 under 35 U.S.C. §102(a) as being anticipated by the TOR2 sequence, Genbank Accession No. AY274119, version AY274119.1, GI29826276 (14 April 2003) **is withdrawn** in view of the amendment and Applicants' presentation of the evidence that the maximum number of identical contiguous nucleotides between the claimed SEQ ID NO:15 and the TOR2 sequence is 7914 (page 20 of the Remarks filed on 19 November 2006).

New Claim Objections

Claims 29 and 32 are objected to for depending from withdrawn claims.

Claims 101 and 125 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 101 recites "an immunogenic formulation comprising a nucleic acid molecule" without identifying what is the immunogen in the immunogen formulation. It is unclear whether the formulation comprises a DNA or an antigenic protein encoded by the DNA.

Claim 125 is rejected for depending from claim 101.

Applicant can obviate this rejection by amending the claim to recite "a nucleic acid molecule comprising at least 8,000 contiguous nucleotides of the nucleotide sequence of SEQ ID NO:15, or a complement thereof, encoding a SARS antigen" or anything the like.

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 175-177 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel biological materials, specifically a host cell comprising a nucleic acid molecule. Since the biological materials are essential to the claimed invention they must be obtainable by a reproducible method set forth in the specification or otherwise readily available to the public. If the biological materials are

not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials.

The specification does not disclose a repeatable process to obtain the biological materials and it is not apparent if the biological materials are readily available to the public. It is noted that Applicant has deposited the isolated hSARS virus (p. 60 of the specification), but there is no indication in the specification as to public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information. Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jeffrey Parkin, Ph.D.
Primary Examiner
24 January 2007

Louise Humphrey, Ph.D.
Assistant Examiner